

## **REMARKS**

Claims 1,8-12, 15, 17-41 are pending. Claims 8-11, 15 and 19 are withdrawn. Claims 2-7, 13, 14 and 16 are canceled.

Support for the “SIS” limitation in claim 1 is found in as-filed claim 7

**The Examiner advised that should claims 6 and 7 be found to be allowable , claims 14 and 16 would be objected to for duplicate claiming.**

Claims 14 and 16 have been canceled.

**Claims 1, 4-7, 12, 14, 16-18 and 20-41 stand rejected under 35 USC § 1112, second paragraph as being indefinite, as the description “substantially two-dimensionally shaped (material)” is unnecessary in light of the newly added limitations.**

Applicants have deleted the “substantially two-dimensionally shaped” limitation from claim 1. Therefore, this rejection should be withdrawn.

**Claims 1, 4-7, 12, 14, 16-18 and 20-41 are rejected under 35 USC § 103(a) as being unpatentable over Gan (U.S. Patent 5,964,807), in view of Bilbo (U.S. 2007/0250177), Li (U.S. 6,764,514), Lim (WO 03/51239), and Moehlenbruck (U.S. Patent 6,723,335).**

**In the March 2009 Amendment ,** Applicants respectfully submitted that Bilbo did not contemplate any folding of the ICL in order to create an annular plug. For example, Example 13 of Bilbo, entitled “Use of a Bioengineered Flat Sheet ICL Prosthesis to Repair the Annulus Fibrosis After Partial Discectomy” states, in part : ... To apply the bioengineered flat sheet ICL prosthesis, it is first trimmed into three or four smaller pieces and then inserted into the annular hole opening.” Similarly, Example 15, entitled “A Time Course Study Using Bioengineered Flat Sheet ICL Prosthesis in Annulus Fibrosus Repair of Pigs”, states, in part, that “A surgical annular defect are created in each exposed disc. Several pieces of connective tissue construct, each about 2 to 5 mm in diameter, are implanted into two defects of each animal.” Therefore, in both of its pertinent

examples, Bilbo relies upon using multiple pieces to create an effective thickness in its implant (and not folding), and so teaches away from the present invention.

**In the April 29, 2009 Office Action,** it appears that the Examiner did not respond to this assertion.

**In this RCE,** Applicants respectfully request that the Examiner respond to Applicants' March 2009 assertion that Bilbo teaches away from the present invention.

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**In the April 29, 2009 Office Action,** the Examiner further responded as follows:

Furthermore, the rationale is based on the fact that one would find it *prima facie* obvious to manipulate the size and shape of the repair material such that it corresponds in size and shape to the defect, or such that the repair material will correlate with the shape and size of the defect upon implantation; this the repair material need not have the exact dimensions as the defect but rather must only be capable of conforming to the size and shape of the defect upon implantation. As such, the repair material would be routinely manipulated to a size and shape that would be appropriate for application to the defect size.

**In this RCE,** Applicants first respectfully submit that the examiner has engaged in hindsight reconstruction of the invention using the specification as a roadmap. First, Applicants respectfully submit that one would find it *prima facie* obvious to provide a ready-made implant having the size and shape of the defect. However, it is by no means obvious to replace a ready-made SIS implant with an SIS implant that must first be molded by the surgeon in order to fit the shape of the defect. Indeed, there is no teaching or even a suggestion of pre-insertion folding of the SIS implant in the four references provided by the examiner in the above rejection.

Second, even if it were somehow obvious to manipulate the size and shape of the SIS repair material such that it corresponds in size and shape to the defect, the examiner has provided no evidence supporting the conclusion that it is obvious to use a thin flat sheet of the claimed dimensions as the starting material for the molding.

Third, even if it were somehow obvious to manipulate the size and shape of the SIS repair material such that it corresponds in size and shape to the defect, Applicants respectfully submit that the prior art only teaches that either i) such manipulation involves the making smaller pieces (as in Bilbo), or ii) such manipulation requires a shape memory material (as in Li).

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**In the March 2009 Amendment,** Applicant respectfully submitted that Gan teaches that its preferred embodiment comprises sintered bioactive glass. As such, it is not readily amenable to folding. Therefore, Gan teaches away from the present invention.

**In the April 29, 2009 Office Action,** the Examiner responded first that the examiner may rely upon the entire disclosure of Gan (not just its preferred embodiment) and second that substitution of a known material such as SIS for the Gan material would yield predictable results and so would be obvious.

**In this RCE,** Applicants respectfully submit that the examiner has first failed to identify which portion of the Gan disclosure is now being relied upon, and second fails to identify why the skilled artisan would be motivated to substitute SIS for Gan's sintered glass material, why the skilled artisan would change the dimensions of the material to that of the claimed dimensions, and why the skilled artisan would be motivated to alter the insertion technique to including a folding step.

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The deficiencies of Gan and Bilbo have been discussed above. Neither Li, Lim nor Moehlenbruck cure these deficiencies. Li's material manipulation disclosure requires the use of a shape memory material, and so excludes any teaching respecting the use of SIS. Lim has been cited only for its GDF-5 disclosure. Moehlenbruck has been cited only for its autologous bone marrow disclosure.

Therefore, this obviousness rejection should be withdrawn.

In addition, please provide any additional extensions of time which may be necessary and charge any fees, such as for presentation of extra claims, which may be due to Deposit Account No. 10-0750, but do not include any payment of issue fees. Should there be any remaining or further questions, the Examiner is requested to contact the undersigned directly.

Respectfully submitted,

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